PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): **Stephen L. Dewey, et al.**

Attorney Docket No.: **BSA 01-29**

Title: **TREATMENT OF ADDICTION AND ADDICTION-RELATED BEHAVIOR**

Assistant Commissioner for Patents
Washington, DC 20231

INFORMATION DISCLOSURE STATEMENT

Sir:

In order to fulfill the requirements of candor and good faith set forth in 37 C.F.R. § 1.56, Applicants submit the following disclosure in accordance with the provisions of 37 C.F.R. § 1.97 and § 1.98.

I. UNITED STATES PATENTS

PATENTEE	PATENT NUMBER	ISSUE DATE
Phillips, Jack	3,639,607	February 1, 1972
Seiler et al.	4,540,582	September 10, 1985
Seiler et al.	4,595,697	June 17, 1986
Frieben et al.	4,621,145	November 4, 1986
Blum et al.	5,189,064	February 23, 1993
Mayer, et al.	5,869,498	February 9, 1999
Chasin, et al.	5,942,241	August 24, 1999
Merrill, et al.	5,948,787	September 7, 1999
Chasin, et al.	5,958,459	September 28, 1999

Oshlack, et al.	5,968,551	October 19, 1999
Caruso, Frank	6,007,841	December 28, 1999
Caruso, Frank	6,054,451	April 25, 2000
Merrill, et al.	6,077,538	June 20, 2000
Nabeshima, et al.	6,107,330	August 22, 2000
Chasin, et al.	6,103,261	August 15, 2000
Sackler, et al.	6,143,322	November 7, 2000
Oshlack, et al.	6,143,353	November 7, 2000

II. FOREIGN PATENT DOCUMENTS

COUNTRY	PATENT NO.	ISSUE DATE
PCT	WO 89/03211	April 20, 1989
PCT	WO 98/00130	January 8, 1998
PCT	WO 99/21540	May 6, 1999
PCT	WO 00/07583	February 17, 2000
PCT	WO 00/23059	April 27, 2000
PCT	WO 00/44374	August 3, 2000
PCT	WO 00/50020	August 31, 2000
PCT	WO 00/61140	October 19, 2000
PCT	WO 00/66108	November 9, 2000

III. NON-PATENT PUBLICATIONS

1. Morgan et al., "Longterm Cocaine Administration May Alter Specific Gabaergic Pathways", Abstracts Society for Neuroscience, 23:1942 (1997).

2. Kushner et al., "Comparison of the Effects of Vigabatrin on Cocaine Self-Administration and Food Reinforcement", Abstracts Society for Neuroscience, 23:1942 (1997).

3. Dewey et al., "GABAergic Attenuation of Cocaine-Induced Dopamine Release and Locomotor Activity", Synapse, 25:393-398 (1997).

4. Morgan et al., "Effects of Pharmacologic Increases in Brain GABA Levels on Cocaine-Induced Changes in Extracellular Dopamine", Synapse 28:60-65 (1998).

5. Kushner et al., "Gamma-vinyl GABA Attenuates Cocaine-Induced Lowering of Brain Stimulation Reward Thresholds", Psychopharmacology 133:383-388 (1997).

6. Porter et al., "Antiepileptic Drugs", Basic and Clinical Pharmacology, ed. by Katzung, B.G., Appelton and Lange, Stamford, CT pp. 386-408 (1998).

7. Takada et al., "Drug Dependence Study on Vigabatrin in Rhesus Monkeys and Rats", Arzneim.-Forsch Drug Res 47(II), 1087-1092 (1997).

8. Nisell et al., "Nicotine Dependence, Midbrain Dopamine Systems and Psychiatric Disorders", Pharmacology & Toxicology 76:157-162 (1995).

9. Nisell et al., "Infusion of Nicotine in the Ventral Tegmental Area or the Nucleus Accumbens of the Rat Differentially Affects Accumbal Dopamine Release", Pharmacology & Toxicology, 75:348-352 (1994).

10. Fudala et al., "Pharmacologic Characterization of Nicotine-Induced Conditioned Place Preference", Pharmacol Biochem Behav 22(2) 237-241 (1985)

11. Clarke et al., "Apparent Absence of Nicotine-Induced Conditioned Place Preference in Rats" Psychopharmacology, 92: 84-88 (1987).

12. Clarke et al., " Evidence That Mesolimbic Dopaminergic Activation Underlies the Locomotor Stimulant Action of Nicotine in Rats", The Journal of Pharmacology and Experimental Therapeutics, 246:701-708 (1988).

13. Henningfield et al., "Control of Behavior by Intravenous Nicotine Injections in Human Subjects", Pharmacology Biochemistry & Behavior, 19:1021-1026 (1983).

14. Jarvik et al., "Pharmacological Treatment of Tobacco Dependence", Pharmacology Biochemistry & Behavior, 30:279-294 (1988).

15. Henningfield et al., "Cigarette Smokers Self-Administer Intravenous Nicotine", Pharmacology Biochemistry & Behavior 19:887-890 (1983).

16. Nisell et al., "Systemic Nicotine-Induced Dopamine Release in the Rat Nucleus Accumbens is Regulated by Nicotinic Receptors in the Ventral Tegmental Area", Synapse 16:36-44 (1994).

17. Pontieri et al., "Effects of nicotine on the nucleus accumbens and similarity to those of addictive drugs" Nature 382:255-257 (1996).

18. Di Chiara et al., "Drugs Abused by Humans Preferentially Increase Synaptic Dopamine Concentrations in the Mesolimbic System of Freely Moving Rats", Proc. Natl. Acad. Sci. USA, 85:5274-5278 (1988).

19. Damsma et al., "Lack of Tolerance to Nicotine-Induced Dopamine Release in the Nucleus Accumbens", European Journal of Pharmacology, 168:363-368 (1989).

20. Imperato et al., "Nicotine Preferentially Stimulates Dopamine Release in the Limbic System of Freely Moving Rats" European Journal of Pharmacology, 132:337-338 (1986).

21. Brazell et al., "Acute Administration of Nicotine Increases the *In Vivo* Extracellular Levels of Dopamine, 3,4-Dihydroxyphenylacetic Acid and Ascorbic Acid Preferentially in the Nucleus Accumbens of the Rat: Comparison with Caudate-Putamen", Neuropharmacology 29:1177-1185 (1990).

22. Horan et al., "Nicotine Produces Conditioned Place Preference in Lewis But Not Fischer 344 Rats", Synapse 26:93-94 (1997).

23. Lepore et al., "Conditioned Place Preference Induced By Δ^9-Tetrahydrocannabinol: Comparison with Cocaine, Morphine, and Food Reward", Life Sciences, 56:2073-2080 (1995).

24. Sora et al., "Cocaine reward models: conditioned place preference can be established in dopamine- and in serotonin-transporter knockout mice" Proc. Natl. Acad. Sci. USA 95:7699-7704 (1998).

25. Valentine et al., "Self-Administration in Rats Allowed Unlimited Access to Nicotine" Psychopharmacology, 133:300-305 (1997).

26. Eliot L. Gardner, "6 Brain Reward Mechanisms", Substance Abuse: A Comprehensive Textbook, p.51-85 (1997).

27. Marshall et al., " Presynaptic Nicotinic Modulation of Dopamine Release in the Three Ascending Pathways Studied by In Vivo Microdialysis: Comparison of Naive and Chronic Nicotine-Treated Rats" Journal of Neurochemistry, 68:1511-1519 (1997).

28. M.-F. Chesselet, "Presynaptic Regulation of Neurotransmitter Release in the Brain", Neuroscience 12:347-375 (1984).

29. Lacey et al., "On the Potassium Conductance Increase Activated by $GABA_B$ and Dopamine D_2 Receptors in Rat Substantia Nigra Neurones" Journal of Physiology 401:437-453 (1988).

30. Grant et al., "Vigabatrin: A Review of its Pharmacodynamic an Pharmacokinetic Properties, and Therapeutic Potential in Epilepsy and Disorders of Motor Control" Drugs 41 6:889-926 (1991).

31. Jung et al., "Vinyl GABA (4-amino-hex-5-enoic acid). A New Selective Irreversible Inhibitor of GABA-T: Effects on Brain GABA Metabolism in Mice" Neurochem. 29:797-802 (1977).

32. Tsuji et al., "Activation of Ventral Tegmental $GABA_B$ Receptors Inhibits Morphine-Induced Place Preference in Rats" European Journal of Pharmacology 313:169-173

33. Roberts et al., "Baclofen Suppression of Cocaine Self-Administration: Demonstration Using a Discrete Trials Procedure" Psychopharmacology 131:271-277 (1997).

34. Bolser et al., "The Pharmacology of SCH 50911: A Novel, Orally-Active GABA-B Receptor Antagonist" The Journal of Pharmacology and Experimental Therapeutics 274:1393-1398 (1995).

35. Roberts et al., "Baclofen Attenuates the Reinforcing Effects of Cocaine in Rats" Neuropsychopharmacology 15:417-423 (1996).

36. Derek van der Kooy, "Place Conditioning: A Simple and Effective Method for Assessing the Motivational Properties of Drugs" M.A. Bozarth, Ed., Springer-Verlag, New York, pp. 229-241 (1987).

37. Hurt et al., "A Comparison of Sustained-Release Bupropion and Placebo for Smoking Cessation" The New England Journal of Medicine 337:1195:1202 (1997).

38. Volkow et al., "Imaging Endogenous Dopamine Competition With [^{11}C] Raclopride in the Human Brain" Synapse 16:255-262 (1994).

39. Logan et al., "Graphical Analysis of Reversible Radioligand Binding from Time-Activity Measurements Applied to [N-^{11}C-methyl]-(-)-Cocaine PET Studies in Human Subjects" Journal of Cerebral Blood Flow and Metabolism 10:740-747 (1990).

40. Dewey et al., "A Novel Strategy for the Treatment of Cocaine Addiction" Synapse 30:119-129 (1998).

41. Dewey et al., "Striatal Binding of the PET Ligand ^{11}C-Raclopride is Altered by Drugs that Modify Synaptic Dopamine Levels" Synapse 13:350-356 (1993).

42. Dewey et al. "GABAergic Inhibition of endogenous Dopamine Release Measured *in vivo* with ^{11}C-Raclopride and Positron Emission Tomography" The Journal of Neuroscience 12(10):3773-3780 (1992).

43. Dewey et al., "Effects of Central Cholinergic Blockade on Striatal Dopamine Release Measured with Positron Emission Tomography in Normal Human Subjects" Proc. Natl. Acad. Sci. USA 90:11816-11820 (1993).

44. Buckland et al., "Amphetamine and Vigabatrin Down Regulate Aromatic L-amino acid Decarboxylase mRNA levels" Molecular Brain Research 35:69-76 (1996).

45. Cubells et al., "*In Vivo* Action of Enzyme-Activated Irreversible Inhibitors of Glutamic Acid Decarboxylase and γ-Aminobutyric Acid Transaminase in Retina vs. Brain" The Journal of Pharmacology and Experimental Therapeutics 238:508-514 (1986).

46. Herbert D. Kleber, "Treatment of Cocaine Abuse: Pharmacotherapy" Cocaine Scientific and Social Dimensions p.195-206 (1992).

47. Ritz et al., "Psychostimulant Drugs and a Dopamine Hypothesis Regarding Addiction: Update on recent research" Biochem. Soc. Symp. 59:51-64.

48. Sherif et al., "Basic Aspects of GABA-transmission in Alcoholism, with Particular Reference to GABA-transaminase" European Neuropsychopharmacology 7:1-7(1997).

49. Dewey et al., "A New GABAergic strategy for treating cocaine addiction" J. Nuclear Med. 39:99-100 (1998).

50. Morgan et al., "Vigabatrin Attenuates Cocaine-Induced Changes in Brian Dopamine Concentrations" J. Nuclear Med. 38:11p (1997).

51. Kushner et al., The irreversible Gamma-aminobutyric acid (GABA) transaminase inhibitor Gamma-vinyl-GABA blocks cocaine self-administration in rats" J. Pharmacology and Experimental Therapeutics 290:797-802 (1999).

52. Dewey et al., "A Pharmacologic Strategy for the Treatment of Nicotine Addiction" Synapse 31:76-86 (1999).

53. Meier, et al., "Medicine Merchants/Uses and Abuses, Use of Painkiller Grows Quickly, Along with Widespread Abuse", New York Times, A1 (2001).

Copies of the documents listed above have been previously submitted during the prosecution of the relevant parent applications. Therefore, copies of the documents are not enclosed herein. A separate listing of these publications is also provided on form PT0-1449, also enclosed herewith.

Applicants believe that the application is in condition for examination and favorable consideration. If the Examiner has any questions or comments relating to the present invention, he or she is respectfully invited to contact Applicants' attorney at the telephone number set forth below.

Respectfully submitted,

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